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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127 JEH

January 24, 2002

VIA FEDERAL EXPRESS

Ms. Shirley A. Smith
Chief Operating Officer
Cush Industries Inc.
881 Mountain View Drive
Piney Flats, TN 37686

Warning Letter No. 02-NSV-12

Dear Ms. Smith:

During an inspection of your firm, on December 4-13, 2001, our investigator determined that your facility was manufacturing devices that are adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed deviations from 21 CFR Part 820 including inadequate and incomplete validation of device sterilization cycle, incomplete Device History Records, incomplete written Standard Operating Procedures, no management review of the device quality system, and incomplete Device Master Records.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's Quality System. You are responsible for investigating and determining the causes for the violations identified by the Food and Drug Administration (FDA).

We acknowledge that you have submitted to this office a response dated January 7, 2002, concerning our investigator's observations noted on the Form FDA 483. We have reviewed your response and have the following comments:

1. Items 1, 2, 4, 10, 14, 16, 17, 18 & 19 – These deviations cannot be evaluated until the promised additional response is received.

2. Item 3 – The response provides no additional information than was obtained during the inspection in regard to the location of the biological indicators.

3. Item 5 – The response did not provide acceptable limits for ETO residues.

4. Item 6 – The response did not adequately address the issue of corrugated material being the only criterion for loading a chamber.

5. Item 7 – The response did not address this issue.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no request for Certificates to Foreign Governments will be approved until the violations related to your devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Director, New Orleans District

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Enclosure:
21 CFR Part 820